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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/608,066	06/30/00	ASTATKE	M 0942.4990001

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EXAMINER	
TAYLOR, J	
ART UNIT	**PAPER NUMBER**
1655	16

DATE MAILED: 02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/608,066	ASTATKE ET AL.	
	Examiner	Art Unit	
	Janell Taylor Cleveland	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *1-11, 30-31, and 35-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-29 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. In response to Applicant's Reply to Restriction Requirement, Paper #8, Groups II-V (Claims 12-29 and 32-34) are hereby rejoined. This is based on Applicant's argument that the claims are drawn to closely related subject matter which would not cause a substantial burden upon Examiner to include in a search.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 12-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Gold et al. (USPN 6,020,130).

Claim 12 is drawn to a method for synthesizing a nucleic acid molecule comprising: mixing at least one enzyme with polymerase activity with one or more nucleic acid inhibitors of claim 1 and one or more templates; and incubating said mixture under conditions sufficient to synthesize one or more first nucleic acid molecules complementary to all or a portion of said templates. Claim 13 is drawn to the method of claim 12, wherein said mixing is accomplished under conditions to prevent nucleic acid synthesis and/or to allow binding of said nucleic acid inhibitor to said enzyme with polymerase activity. Claim 14 is drawn to the method of claim 12, wherein

said synthesis is accomplished under conditions sufficient to reduce the inhibitory affect of said nucleic acid inhibitor. Claim 15 is drawn to the synthesis being accomplished in the presence of at least one component selected from nucleotides or primers. Claim 16 is drawn to the template being double stranded. Claim 17 is drawn to making second nucleic acid molecules complementary to first nucleic acid molecules. Claim 18 is drawn to a nucleic acid made by the method of claim 12. Claim 19 is drawn to a method for amplifying a nucleic acid molecule comprising: mixing at least one nucleic acid inhibitor of claim 1 with one or more enzymes with polymerase activity and one or more templates; and incubating said mixture under conditions sufficient to synthesize one or more first nucleic acid molecules complementary to all or a portion of said templates. Claim 20 is drawn to the method of claim 19, wherein said mixing is accomplished under conditions to prevent nucleic acid synthesis and/or to allow binding of said nucleic acid inhibitor to said enzyme with polymerase activity. Claim 21 is drawn to the method of claim 19, wherein said synthesis is accomplished under conditions sufficient to reduce the inhibitory affect of said nucleic acid inhibitor. Claim 22 is drawn to the synthesis being accomplished in the presence of at least one component selected from nucleotides or primers. Claim 23 is drawn to the template being double stranded. Claim 24 is drawn to a nucleic acid made by the method of claim 12.

Gold et al. teach "The present invention includes methods of identifying and producing nucleic acid ligands to DNA polymerases. Specifically included are methods for identifying nucleic acid ligands to thermostable DNA polymerases useful in the Polymerase Chain Reaction, including the Taq and Tth polymerases and the nucleic

acid ligands so identified and produced. More particularly, *DNA sequences are provided that are capable of binding specifically to the Taq and Tth polymerases respectively, thereby inhibiting their ability to catalyze the synthesis of DNA at ambient temperatures.* The method of this invention can be extended to identifying and producing nucleic acid ligands to any thermostable DNA polymerase and the ligands so identified and produced." (Col. 5, line 60 through Col. 6, line 6). Gold goes on to say that included in the invention is an improved method of performing PCR (Col. 6). Therefore Gold teaches all of the limitations of claims 12-24.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gold et al.

Claim 32 is drawn to a method for amplifying a double stranded DNA molecule, comprising providing a first and second primer, wherein said first primer is complementary to a sequence within or at or near the 3' termini of the first strand of DNA molecule and said second primer is complementary to a sequence within or at or near the 3' termini of the second strand of said DNA molecule and one or more nucleic acid inhibitors prevent or inhibit nucleic acid synthesis; hybridizing said first strand and said second primer to said second strand to form hybridized molecules; incubating said

hybridized molecules under conditions sufficient to allow synthesis of a third DNA molecule complementary to all or a portion of said first strand and a fourth DNA molecule complementary to all or a portion of said second strand; denaturing and repeating one or more times. Claim 33 is drawn to a method of preparing cDNA from mRNA, comprising mixing one or more mRNA templates, one or more reverse transcriptases, and with one or more nucleic acid inhibitors of claim 1; and incubating said mixture under conditions sufficient to synthesize one or more cDNA molecules complementary to all or a portion of said templates. Claim 34 is drawn to the method of claim 33, wherein said mixing is accomplished under conditions sufficient to prevent nucleic acid synthesis and/or allow binding of said nucleic acid inhibitor to said reverse transcriptase.

Gold et al. teach "The present invention includes methods of identifying and producing nucleic acid ligands to DNA polymerases. Specifically included are methods for identifying nucleic acid ligands to thermostable DNA polymerases useful in the Polymerase Chain Reaction, including the Taq and Tth polymerases and the nucleic acid ligands so identified and produced. More particularly, *DNA sequences are provided that are capable of binding specifically to the Taq and Tth polymerases respectively, thereby inhibiting their ability to catalyze the synthesis of DNA at ambient temperatures.* The method of this invention can be extended to identifying and producing nucleic acid ligands to any thermostable DNA polymerase and the ligands so identified and produced." (Col. 5, line 60 through Col. 6, line 6). Gold goes on to say that included in the invention is an improved method of performing PCR (Col. 6).

Gold et al. do not teach providing a first and second primer which hybridize at or near the 3' termini, or preparing cDNA from mRNA.

These would have been obvious, however, to one of ordinary skill in the art at the time of the invention. This is because providing primers which hybridize at the 3' termini, as well as preparing cDNA from mRNA, are both well known in the art and are standard procedures for synthesizing/amplifying nucleic acids. Gold et al. teach the use of PCR, and these were both well known components of PCR at the time of the invention.

6. Claims 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gold et al. in view of Langmore et al. (USPN 6,117,634).

Claim 25 is drawn to a method for sequencing a nucleic acid molecule comprising: mixing at least one nucleic acid molecule to be synthesized with one or more nucleic acid inhibitors of claim 1, one or more enzymes having polymerase activity, and one or more terminating agents; incubating said mixture under conditions sufficient to synthesize a population of molecules complementary to all or a portion of said molecules to be sequenced. Claim 26 is drawn to the method of claim 25, wherein said mixing is accomplished under conditions to prevent nucleic acid synthesis and/or to allow binding of said nucleic acid inhibitor to said enzyme with polymerase activity. Claim 27 is drawn to the method of claim 25, wherein said synthesis is accomplished under conditions sufficient to denature said nucleic acid inhibitor. Claim 28 is drawn to the synthesis being accomplished in the presence of at least one component selected from nucleotides or primers. Claim 29 is drawn to the template being double stranded.

Gold et al. teach "The present invention includes methods of identifying and producing nucleic acid ligands to DNA polymerases. Specifically included are methods for identifying nucleic acid ligands to thermostable DNA polymerases useful in the Polymerase Chain Reaction, including the Taq and Tth polymerases and the nucleic acid ligands so identified and produced. More particularly, *DNA sequences are provided that are capable of binding specifically to the Taq and Tth polymerases respectively, thereby inhibiting their ability to catalyze the synthesis of DNA at ambient temperatures*. The method of this invention can be extended to identifying and producing nucleic acid ligands to any thermostable DNA polymerase and the ligands so identified and produced." (Col. 5, line 60 through Col. 6, line 6). Gold goes on to say that included in the invention is an improved method of performing PCR (Col. 6).

Gold et al. do not teach sequencing.

Langmore et al teach "In one embodiment, the present invention contemplates a method for sequencing nucleic acid, comprising: a) providing: i) nucleic acid template capable of being double-stranded, ii) a polymerase having a polymerase activity and a 5'-3' exonuclease activity, iv) a nucleic acid precursor, and iii) a terminating agent; b) mixing said polymerase, said precursors, said terminating agents and said template to create a reaction under conditions where said template is substantially double-stranded; and c) detecting product of said reaction under conditions whereby the nucleic acid sequence of at least a portion of said template is revealed. In one embodiment said template capable of being double-stranded comprises single-stranded nucleic acid that, upon cooling becomes substantially double-stranded." (Col. 4, lines 1-15).

It would have been obvious to one of ordinary skill in the art at the time of the invention that sequencing would have been an obvious variation on the amplification/synthesis reactions carried out by Gold. This is because it was well known in the art at the time of the invention that sequencing necessitated the same basic steps as amplification by PCR, and necessitated a polymerase whose activity would have been inhibited by the inhibitor of the present method. For this reason, it would have been obvious to carry out a sequencing method using the inhibitor of Gold.

Summary

7. Claims 1-11, 30-31, and 35-59 are withdrawn from consideration. Claims 12-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Gold et al. (USPN 6,020,130). Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gold et al. Claims 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gold et al. in view of Langmore et al. No claims are free of the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland, whose telephone number is (703) 305-0273.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature relating to this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 305-3014 or 305-4227. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland

February 8, 2001

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

2/9/01